

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-656V

Filed: September 29, 2015

UNPUBLISHED

STEPHANIE KUHN,
the parent and natural guardian of
a minor child, L.K.,

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Chief Special Master Nora Beth Dorsey

Petitioner,

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Entitlement; Ruling on the Record;
Decision Without a Hearing;

v.

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Lack of a Medical Opinion;
Insufficient Proof of Causation;

SECRETARY OF HEALTH
AND HUMAN SERVICES,

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Lack of Proximal Temporal Relationship;
Multiple Vaccines Including the

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Rotavirus Vaccine; Intussusception;
Special Processing Unit ("SPU")

Randall Knutson, Knutson and Casey Law Firm, Mankato, MN, for petitioner.
Justine Walters, Department of Justice, Washington, DC, for respondent.

DECISION¹

On July 24, 2014, Stephanie Kuhn filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq.,² [the "Vaccine Act" or "Program"] on behalf of her minor child, L.K. Petitioner alleges that the diphtheria-tetanus-acellular pertussis ("DTaP"), inactivated polio ("IPV"), Haemophilus influenzae ("Hib"), hepatitis B ("Hep B"), pneumococcal conjugate ("PCV"), and rotavirus vaccinations administered to L.K. on August 4, 2011 caused him to develop

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post this decision on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002 § 205, 44 U.S.C. § 3501 (2006). In accordance with the Vaccine Rules, each party has 14 days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted ruling. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be deleted from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

intussusception.³ Petition at ¶¶ 4-6. Petitioner further alleges that “L.K. continues to have medical issues [and] will require future follow-up care and monitoring.” Petition at ¶ 7. The case was assigned to the Special Processing Unit of the Office of Special Masters.

Under the Vaccine Act, compensation may not be awarded “based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” § 13(a)(1). Petitioner has failed to file the report of a medical expert, and the medical records do not support petitioner’s claims. For the reasons discussed below, petitioner has failed to demonstrate that she is entitled to compensation. The petition is dismissed for insufficient proof.

I. Procedural History

Petitioner filed her petition on July 24, 2014, and medical records several weeks later. The initial status conference was held telephonically on September 2, 2014. During the call, the OSM staff attorney managing this case discussed the lack of evidence of intussusception and noted that, even if proven to be intussusception, the onset of L.K.’s injury occurred too late to constitute a proximal temporal relationship between vaccination and injury. Respondent’s counsel added that her client also believed there was insufficient proof that L.K. had experienced the residual effects of any injury for more than six months. She also raised the possibility of an alternative cause (salmonella) for L.K.’s injury. Respondent filed her Rule 4(c) report setting forth her objections to compensation on October 1, 2014.

Thereafter, petitioner was ordered to file a status report indicating whether she intended to proceed with her claim and, if continuing, to provide “a date by which she [could] file an expert report supporting her claim and addressing the issues raised by respondent.” Order, issued Oct. 6, 2014, at 2. Over the next six months, petitioner was granted additional time on four occasions as she sought a specialist to opine in her case. See Orders, issued Nov. 7, 2014; Dec. 4, 2014; Jan. 16, 2015; Feb. 19, 2015. Petitioner was unable to obtain an expert opinion in support of her claim and filed a motion for a ruling on the record on April 20, 2015.⁴

³ Intussusception is “the prolapse of one part of the intestine into the lumen of an immediately adjoining part.” DORLAND’S ILLUSTRATED MEDICAL DICTIONARY (“DORLAND’S”) at 947 (30th ed. 2003).

⁴ Petitioner sought a medical opinion from one of L.K.’s treating doctors, pediatric surgeon Dr. Walter Pipkin. Motion, filed Nov. 7, 2014, at 1. On January 15, 2015, petitioner reported that the Dr. Pipkin verbally indicated that he believed “the vaccination caused L.K.’s intussusception and continuing medical issues” but requested a phone call with petitioner’s attorney to discuss the matter further. Motion, filed Jan. 1, 2015, at 1. During the subsequent phone call, Dr. Pipkin “indicated that he could not definitively relate the vaccination to L.K.’s Intussusception.” Motion, filed Feb. 17, 2015, at 1. Petitioner requested an additional 60 days to meet with another specialist. Id. In her motion for a ruling on the record filed three months later, petitioner indicate she was

Petitioner indicated her request was “based on all documents and exhibits filed to date.” Motion for a Ruling on the Record at 1. After being ordered to identify the specific medical records which support her claim (see order, issued Apr. 28, 2015, at 2), petitioner filed a notice listing exhibit and page numbers. Response, filed May 28, 2015. Respondent filed her response to petitioner’s motion on June 2, 2015.

The matter is now ripe for adjudication.

II. Medical History

L.K. was born on June 1, 2011. He was jaundiced and had a benign rash⁵ but was assessed as normal during his newborn examination. It was noted that he was being bottle fed. Exhibit 7 at 8. At his one month well-child visit, L.K. was observed to be gassy with increased congestion. His pediatrician thought he might have colic. He prescribed Mylicon (infant gas drops) and instructed L.K.’s mother to switch to a soy formula. Exhibit 7 at 3.

On July 18, 2011, L.K. was taken to the emergency room at the Medical College of Georgia (“MCG”) because he had been inconsolable for the last twenty four hours, had not had a bowel movement since 2:00 am the previous morning, and was vomiting and arching his back. His mother indicated that, after trying a soy formula, she had switched back to L.K.’s regular formula. Exhibit 8 at 1. L.K. was observed to be “excessively fussy” but tolerating his formula. Id. at 2. He was diagnosed with reflux and a corneal abrasion. Id. During a follow-up appointment with his pediatrician, L.K. was prescribed Zantac. Exhibit 7 at 4.

When L.K. returned to his pediatrician for his two month well-child visit on August 1, 2011, it was noted that his gastroesophageal reflux disease (“GERD”) was “much better” and his parents were instructed to continue administering Zantac. Exhibit 7 at 2. At this visit, L.K. received the vaccinations alleged to have caused his injury. Exhibit 7 at 2; see also exhibit 7 at 1 (L.K.’s record of vaccinations).⁶

L.K. returned to his pediatrician on August 11, 2011. It appears the primary reason for the visit was the rash L.K. had experienced on his face and head since birth (diagnosed as eczema). However, the record also indicates that L.K. had suffered a

“unable to locate a specialist to address causation in this matter.” Motion for a Ruling on the Record, filed Apr. 20, 2015, at 1.

⁵ Throughout the remainder of the records, L.K. is noted to have “baby acne” and “eczema.” See, e.g., exhibit 7 at 3-4.

⁶ Although the vaccination record filed as exhibit 3 lists Rotatrix as the rotavirus vaccine administered to L.K., his pediatric records indicate he received Rotateq. Exhibit 7 at 1. Since all rotavirus vaccines are listed on the Vaccine Injury Table, the exact brand administered to L.K. does not affect petitioner’s claim. See 42 C.F.R. § 100.3 (2011).

temperature of 100.1 degrees Fahrenheit the previous day and was producing a soft bowel movement every three to four days. His parents were instructed to continue Zantac and were referred to pediatric surgery. Exhibit 7 at 4.

L.K. saw a pediatric surgeon at MCG (Dr. Pipkin) two weeks later on August 25, 2011. They reported L.K. was having abdominal distension which resolved with a bowel movement every three to four days, adding that L.K. cried and grimaced when attempting to produce a bowel movement. They described L.K.'s bowel movements as soft after consuming prune juice and without blood. Exhibit 8 at 4. Dr. Pipkin diagnosed L.K. with anal sphincter spasm and instructed L.K.'s mother to perform anal dilations. Id. at 5. At a follow-up appointment on September 15, 2011, Dr. Pipkin described L.K. as without abdominal pain, constipation, vomiting, nausea, or diarrhea. Exhibit 8 at 6. He indicated L.K.'s mother should increase and then taper off dilations. Id. at 7.

Two days later on September 17, 2011, L.K. was admitted to MCG with complaints of fever, diarrhea, and intermittent abdominal pain. According to his mother, he was not vomiting and had been experiencing daily bowel movement. He was observed to have bloody, currant jelly stools. Exhibit 8 at 8. Upon examination, he was determined to be in no acute distress with a soft, non-tender, and non-distended abdomen and normal bowel sounds. Id. at 9.

X-rays and a limited sonogram of the abdomen showed evidence of intussusception. Exhibit 8 at 9; see id. at 17-19 (results of x-rays and ultrasound). A barium enema was performed, "which showed filling of the entire rectum and colon" and no radiological evidence of intussusception. Id. at 9; see id. at 20 (results of enema). L.K. was admitted for observation but discharged the next day. Although he had continued diarrhea, there was no further blood in the diarrhea and no witnessed episodes of pain. He was feeding normally. Id. at 9. Initially, L.K.'s discharge diagnosis was listed as intussusception (id.), but the records were later amended to indicate diagnoses of "Other Symptoms Involving Digestive System" and "Intussusception Intestine," both described as billing diagnoses. Id. at 16. A summary was added indicating that intussusception had been ruled out by barium enema and that no acute surgical intervention was needed. Id.

Two days later, L.K. returned to the emergency room at MCG with "increased irritability" and "recurrent bloody stools." Exhibit 8 at 21. L.K. was admitted and a second x-ray and barium enema were performed. After no evidence of intussusception was seen on the x-ray (id. at 27-28) or barium enema (id. at 29-30), additional testing was performed. The discharge diagnosis for this hospitalization was listed as "intolerance of formula." Id. at 22.

During a follow-up appointment on October 5, 2011, Dr. Pipkin reported that L.K.'s stool cultures had tested positive for salmonella and described his history as "significant for anal spasm, salmonella, suspected intussusception, and eczema." Exhibit 8 at 31. He characterized L.K.'s current condition as "resolved salmonella gastroenteritis." Id. at 33. At his four month well-child visit on October 31, 2011, he was described as having had "[p]ossible intussusception, reduced if it was there" and "recent salmonella." Exhibit 9 at 5.

L.K. did not visit his pediatrician again until December 15, 2011, when he was seen for a runny nose, cough, congestion, and low grade fever. Exhibit 9 at 8. The remaining pediatric records describe ear infections and other childhood illnesses, but no symptoms which would be attributed to intussusception. When mentioned, L.K.'s bowel movement issues are described as resolved. E.g., exhibit 9 at 12.

III. Applicable Legal Standards

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if the vaccinee for whom she seeks compensation has “sustained, or endured the significant aggravation of any illness, disability, injury, or condition” set forth in the Vaccine Injury Table (the Table). § 11(c)(1)(C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. § 14(a). If petitioner establishes that the vaccinee has suffered a “Table Injury,” causation is presumed.

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, petitioner must prove that the administered vaccine caused injury to receive Program compensation on behalf of the vaccinee. § 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a “non-Table or [an] off-Table” claim and to prevail, petitioner must prove her claim by preponderant evidence. § 13(a)(1)(A). This standard is “one of . . . simple preponderance, or ‘more probable than not’ causation.” Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing Hellebrand v. Sec’y of Health & Human Servs., 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)). The Federal Circuit has held that to establish an off-Table injury, petitioners must “prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Shyface v. Sec’y of Health & Human Servs., 165 F.3d 1344, 1351 (Fed. Cir. 1999). Id. at 1352. The received vaccine, however, need not be the predominant cause of the injury. Id. at 1351.

The Circuit Court has indicated that petitioners “must show ‘a medical theory causally connecting the vaccination and the injury’” to establish that the vaccine was a substantial factor in bringing about the injury. Shyface, 165 F.3d at 1352-53 (quoting Grant v. Sec’y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury.’” Id. The Federal Circuit subsequently reiterated these requirements in its Althen decision. See 418 F.3d at 1278. Althen requires a petitioner

to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the

vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of Althen must be satisfied. Id.

Section 11(c)(1) also contains requirements concerning the type of vaccination received and where it was administered, the duration or significance of the injury, and the lack of any other award or settlement. See § 11(c)(1)(A),(B),(D) and (E). With regard to duration, a petitioner must establish she

(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization **and** surgical intervention.

§ 11(c)(1)(D) (emphasis added).

IV. Analysis of Petitioner's Claim

Petitioner alleges that the vaccinations L.K. received on August 4, 2011 caused him to suffer intussusception, which was diagnosed during two hospitalizations on September 17 and 20, 2011. Petition at ¶¶ 4-6; exhibit 2 at ¶¶ 5, 7 (petitioner's affidavit). Relying solely on the filed medical records, petitioner has failed to provide sufficient evidence regarding several Vaccine Act requirements.

1. The Alleged Injury - Intussusception

Petitioner has failed to show that L.K. suffered the injury petitioner alleges. Although intussusception was initially suspected, it was ruled out by a barium enema performed on September 17, 2011. Exhibit 8 at 20. Subsequent x-rays and a second barium enema showed no evidence of intussusception. Id. at 27-30.

In support of her claim, petitioner points to earlier entries made when intussusception was suspected. See Notice, filed May 28, 2015. Many of these entries clearly state they are for billing purposes (exhibit 8 at 16) or that intussusception was one of several "differential" diagnoses.⁷ It was ultimately determined that L.K. suffered from salmonella, which would account for L.K.'s symptoms and condition. See exhibit 8 at 33.

⁷ Exhibit 8 at 12. Intussusception was listed as a differential diagnosis along with gastroenteritis, viral syndrome, and intestinal malrotation. A differential diagnosis is "the determination of which one of two or more diseases or conditions a patient is suffering from, by systematically comparing and contrasting their clinical findings." DORLAND'S at 507. Thus, this entry shows only that intussusception was considered.

Although L.K. could have suffered from intussusception, it was resolved by the first barium enema he received,⁸ and only one medical record mentions that possibility. Exhibit 8 at 21 (indicating intussusception was “reduced” by the barium enema). Moreover, the evidence shows L.K. experienced salmonella. Since L.K.’s symptoms are explained by that diagnosis, it is unlikely that he also experienced intussusception.

Thus, petitioner has failed to offer preponderant evidence that L.K. suffered intussusception.

2. Causation

Even if petitioner could show that L.K. suffered intussusception, she has not established that the vaccinations he received on August 4, 2011, caused it. The Vaccine Injury Table has been amended to include a Table Injury for intussusception following the administration of the rotavirus vaccine, but the change is applicable only to petitions filed after July 23, 2015, and thus, does not apply to petitioner’s claim.⁹ Since there was no Table Injury for intussusception on the version applicable to her claim (see 42 C.F.R. § 100.3 (2011)), petitioner must prove causation-in-fact. She must meet the three prong test set forth in Althen.

Petitioner has not identified the particular vaccination she believes caused L.K.’s condition and has supplied no medical theory regarding any of the vaccinations he received. The undersigned does recognize, however, that the rotavirus can caused intussusception, and L.K. did receive that vaccination.

Petitioner has not, however, provided any evidence that the rotavirus vaccine L.K. received caused him to suffer intussusception in this instance. None of L.K.’s treating doctors attributed L.K.’s condition to the vaccinations he received on August 4, 2011, and petitioner was unable to obtain a medical opinion supporting causation from his treating doctors or another expert.

⁸ See Parsley v. Sec’y of Health & Human Servs., No. 08-781V, 2011 WL 2463539, at *4 n.15, 7 (Spec. Mstr. Fed. Cl. May 27, 2011) (indicating that a barium enema can sometimes reduce intussusception).

⁹ 42 C.F.R. § 100.3 (2015); see also National Vaccine Injury Compensation Program: Addition of Intussusception as Injury for Rotavirus Vaccines to the Vaccine Injury Table, 80 Fed. Reg. 35,848 (June 23, 2015) (to be codified at 42 C.F.R. pt. 100) (indicating the final rule becomes effective July 23, 2015 and applies only to petitions filed after that date. Petitioner filed this claim approximately one year earlier, July 24, 2014). Even if this change applied to petitioner’s claim, L.K.’s injury would not qualify as a Table Injury because onset occurred more than 40 days after vaccination. In order to qualify as a Table Injury, onset must have occurred 1 to 21 days after vaccination. 42 C.F.R. § 100.3(a)(XI). Moreover, an alternative explanation (salmonella) for L.K.’s symptoms exists. See 42 C.F.R. § 100.3(b)(3)(ii)(B).

Furthermore, the onset of L.K.'s condition occurred more than 40 days after vaccination - too late to constitute a proximal temporal relationship between vaccination and injury. As discussed in the final rule regarding the recent Table change, intussusception caused by the rotavirus vaccine generally occurs one to seven days after vaccination. National Vaccine Injury Compensation Program: Addition of Intussusception as Injury for Rotavirus Vaccines to the Vaccine Injury Table, 80 Fed. Reg. 35,848 (June 23, 2015) (to be codified at 42 C.F.R. pt. 100). Petitioner's claim involves an allegation of onset more than 40 days after vaccination, later even than the more generous 21 days allowed under the table change. Id.

Thus, petitioner has failed to offer preponderant evidence of causation.

3. Statutory Requirement – Six Month or Inpatient Surgery

Ignoring all other defects, petitioner still would not be entitled to compensation under the Vaccine Program because she has failed to establish L.K. suffered the effects of his alleged intussusception for more than six months or that the alleged intussusception required inpatient hospitalization and surgical intervention. See § 11(c)(1)(D).

Although L.K. was hospitalized on two occasions, there is no evidence or even allegation that he required surgical intervention. See Petition at ¶ 5 (alleging only that L.K. was hospitalized). Petitioner argues only that L.K. suffered residual effects of the alleged intussusception; however, the medical records offer no support for her claim.

V. Conclusion

Petitioner has failed to offer the opinion of a medical expert, and the medical records filed do not support her allegations. She has failed to demonstrate that L.K. suffered the injury alleged, that his injury was caused by any of the vaccinations he received, and that he suffered the residual effects of his injury for more than six months or required inpatient hospitalization and surgical intervention.

Petitioner has failed to establish that she is entitled to compensation under the Vaccine Act. **This case is dismissed for insufficient proof.**

The clerk of the court is directed to enter judgment in accordance with this decision.¹⁰

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master

¹⁰ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party filing a notice renouncing the right to seek review.